EXHIBIT BB

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

AQUESTIVE THERAPEUTICS, INC., Plaintiff, v. BIODELIVERY SCIENCES INTERNATIONAL, INC., Defendant.	Civil Action No. 5:19-CV-505-D

PLAINTIFF'S NOTICE OF THIRD-PARTY SUBPOENA
***DUCES TECUM* AND *AD TESTIFICANDUM* TO ARX, LLC**

PLEASE TAKE NOTICE that pursuant to the Federal Rules of Civil Procedure, Plaintiff Aquestive Therapeutics, Inc., by and through its counsel, will serve the attached Subpoena to Produce Documents, Information, or Objects or to Permit Inspection on a Premises in a Civil Action on ARx, LLC ("ARx").

PLEASE TAKE FURTHER NOTICE that pursuant to the Federal Rules of Civil Procedure, Plaintiff Aquestive, by and through its counsel, will serve the attached Subpoena to Testify at a Deposition in a Civil Action on ARx.

Date: January 11, 2022.

Respectfully submitted,

/s/ E. Bradley Evans

E. Bradley Evans
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Local Rule 83.1 Counsel for Aquestive Therapeutics, Inc.

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Attorneys for Aquestive Therapeutics, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 11, 2022, I have served the foregoing documents on all counsel of record.

/s/ E. Bradley Evans

WARD AND SMITH, P.A.
Post Office Box 8088
Greenville, NC 27835-8088
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UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Aquestive Therapeutics, Inc.
Plaintiff
v.
BioDelivery Sciences International, Inc.
Defendant

Civil Action No. 5:19-cv-00505-D

SUBPOENA TO PRODUCE DOCUMENTS, INFORMATION, OR OBJECTS OR TO PERMIT INSPECTION OF PREMISES IN A CIVIL ACTION

To: ARx, LLC at 400 Seaks Run Road, Glen Rock, PA 17327

(Name of person to whom this subpoena is directed)

☑ *Production:* **YOU ARE COMMANDED** to produce at the time, date, and place set forth below the following documents, electronically stored information, or objects, and to permit inspection, copying, testing, or sampling of the material: See Attachment A.

Place:	Date and Time:
Steptoe & Johnson LLP 1330 Connecticut Avenue NW Washington, DC 20036	1/31/2022 9:00am ET, or at such a date, time, and location to be agreed upon by counsel

☑ *Inspection of Premises:* **YOU ARE COMMANDED** to permit entry onto the designated premises, land, or other property possessed or controlled by you at the time, date, and location set forth below, so that the requesting party may inspect, measure, survey, photograph, test, or sample the property or any designated object or operation on it.

Place:	Date and Time:
ARx, LLC 400 Seaks Run Road Glen Rock, PA 17327	4/6/2022 9:00am ET, or a mutually agreed upon date TBD based on the claim construction schedule

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 01/11/2022

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Aquestive Therapeutics, Inc., who issues or requests this subpoena, are:
E. Bradley Evans, Ward & Smith, P.A., Post Office Box 8088, Greenville, NC 27835,
ebe@wardandsmith.com, (252) 215-4025

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 5:19-cv-00505-D

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named person as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

DEFINITIONS

1. The terms "Plaintiff" and "Aquestive" mean Plaintiff Aquestive Therapeutics, Inc., and include, without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of Aquestive, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Aquestive.

2. The terms "Defendant" and "BDSI" mean Defendant BioDelivery Sciences International, Inc., and include, without limitation, all parents, subsidiaries, affiliates, divisions and other entities owned or controlled by Defendant, if any; all officers, directors, employees, partners, agents, attorneys, representatives and owners (whether direct or indirect and legal, beneficial or otherwise) of entities owned or controlled by Defendant, if any, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Defendant or of any subsidiary, affiliate, division or entity owned or controlled by Defendant.

3. The terms "ARx," "You" and "Your" mean ARx, LLC, and include, without limitation, all parents, subsidiaries, affiliates, divisions and other entities owned or controlled by You, if any; all officers, directors, employees, partners, agents, attorneys, representatives and owners (whether direct or indirect and legal, beneficial or otherwise) of entities owned or controlled by You, if any, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of You or of any subsidiary, affiliate, division or entity owned or controlled by You.

4. The term "the '167 Patent" means U.S. Pat. No. 8,765,167.

5. The term "BDSI's NDA" means BDSI's New Drug Application ("NDA") No. 207932, submitted under 21 U.S.C. § 355(b)(2), seeking approval to manufacture, market and sell

BELBUCA throughout the United States, which was approved by the FDA on October 23, 2015, including any amendments and communications to or from the FDA relating to the NDA.

6. The terms "BELBUCA" and "Accused Product" mean BDSI's BELBUCA® (buprenorphine) buccal films that are the subject of BDSI's NDA in the following doses of buprenorphine: 75, 150, 300, 450, 600, 750, and 900 mcg.

7. The term "FDA" means the United States Food and Drug Administration.

8. The terms "Person" and "Persons" mean any individual or entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

9. The term "Entity" means any entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

10. The term "Third Party" means and includes any Person or Entity other than Defendant and Plaintiff.

11. The term "communication" means the transmission of information (in the form of facts, ideas, inquiries or otherwise), whether orally or in writing (e.g., by fax, email, or any other means or medium), and includes without limitation all documents reflecting or concerning such communications.

12. The terms "thing" or "things" shall be defined as synonymous in meaning and equal in scope to the use of that term in Fed. R. Civ. P. 34(a) and includes any tangible object other than a document.

13. The term “document” is used in the broadest sense contemplated by Federal Rule of Civil Procedure 34 and includes the terms “writings and recordings,” “photographs,” “originals,” and “duplicate” as defined in Federal Rule of Evidence 1001 and includes, without limitation, any and all tangible documents and things responsive to the document request as well as any other information regardless of the form in which the information has been stored, including electronically stored information within Your possession, custody, or control.

14. The term “electronically stored information” means any document, communication, code, architecture, internal software comments, or any other data or information present or stored on any computer, internal or external hard drive, jump drive, diskette, compact disc, database, server, or any other device or system capable of storing electronic files or information.

15. The terms “reflecting,” “concerning,” “regarding,” “relating to,” or “referring to” mean all documents or information that comprises, evidences, constitutes, describes, explicitly or implicitly refers to, was reviewed in conjunction with, or was generated as a result of the subject matter of the request, including but not limited to all documents that reflect, record, memorialize, discuss, evaluate, consider, review, report, or relate to the subject matter of the request.

16. The term “employee” means any person currently or formerly serving, acting, or existing as an employee or agent, including employees, agents, attorneys, partners, associates, financial advisors, consultants, investigators, and any other person acting on behalf of the person referred to, pursuant to the authority of the person referred to, or subject to the control of the person referred to.

17. The term “identify” when used with respect to an activity, an occasion or a transaction means and refers to providing: the date of the act; the identity of the persons who

participated in the act; the identity of each person who witnessed such act; and a general description of the act.

18. The term "identify" when used with respect to persons means to state the person's name, title (or job description), present or last known employer or business association, and present or last known address.

19. The term "identify" when used with respect to documents means to provide the following information irrespective of whether the document is deemed privileged or subject to any claim of privilege:

a) the title or other means of identification of the document;

b) the date of the document;

c) the author of the document;

d) the recipient or recipients of the document;

e) the subject matter of the document;

f) the present location of any and all copies of the document in the possession, custody or control of Defendants; and

g) the names and current addresses of any and all persons who have possession, custody, or control of the document or copies thereof.

20. "And" and "or" shall be construed conjunctively and disjunctively so as to acquire the broadest possible meaning.

21. The terms "any," "all," or "each" shall be construed as "any, all and each."

22. The singular and masculine form of a noun or pronoun shall embrace, and shall be read and applied as, the plural or the feminine or neuter, as the particular context makes appropriate or permits to obtain the broadest possible meaning.

23. The use of the singular form of any word shall include the plural and vice versa.

INSTRUCTIONS

The following instructions apply to each specific request unless otherwise explicitly stated.

1. You are to search all Documents within your possession, custody, or control, wherever located, including any Documents placed in storage facilities or in the possession of any employee, agent, representative, attorney, investigator, or other person acting or purporting to act on your behalf (whether located at his/her residence or place of business), in order to fully respond to the requests herein.

2. You are to produce Documents from any single file in the same order as they were found in such file, including any labels, files, folders and/or containers in which such Documents are located in or associated with. If copies are produced in lieu of the originals, such copies should be legible and bound, stapled, or segregated in the same manner as the original.

3. If you do not produce each document or thing requested herein as they are kept in the usual course of business, you must organize and label the Documents or things produced to correspond with the particular document request to which the document or thing is responsive.

4. You are to produce all Documents which are responsive in whole or in part to any of the requests herein in full, without abridgement, abbreviation, or expurgation of any sort. If any such Documents cannot be produced in full, produce the document to the extent possible.

5. You are required to produce not only the original or an exact copy of the original of all Documents or things responsive to any of the requests herein, but also all copies of such Documents or things which bear any notes or markings not found on the originals and all preliminary, intermediate, final, and revised drafts or embodiments of such Documents or things.

You are also required to produce all versions of the foregoing Documents stored by a computer internally, on disk, on CD-ROM, or on tape

6. You are to produce any purportedly privileged document containing non-privileged matter, with the purportedly privileged portion excised or redacted.

7. If any of the Documents requested herein are no longer in your possession, custody, or control, you are requested to identify each such requested document by date, type of document, person(s) from whom sent, person(s) to whom sent, and person(s) receiving copies, and to provide a summary of its pertinent contents.

8. If any document responsive to these requests has been destroyed, describe the content of such document, the location of any copies of such document, the date of such destruction, and the name of the person who ordered or authorized such destruction.

9. Electronic and computerized materials must be produced in an intelligible format or together with a description of the system from which it was derived sufficient to permit tendering of the material intelligible.

10. If production of any document requested herein is withheld on the basis of a claim of privilege, each withheld document shall be separately identified in a privileged document list. The privileged document list must identify each document separately, specifying for each document at least: (1) the date; (2) author(s)/sender(s); (3) recipient(s), including copy recipients; and (4) general subject matter of the document. The sender(s) and recipients(s) shall be identified by position and entity (corporation or firm, etc.) with which they are employed or associated. If the sender or the recipient is an attorney or a foreign patent agent, he or she shall be so identified. The type of privilege claimed must also be stated, together with a certification that all elements of the claimed privilege have been met and have not been waived with respect to each document.

11. If any of the documents or things requested herein are considered "confidential business information," as that term is defined in the Protective Order attached hereto as Exhibit 1, such documents or things shall be produced subject to the terms and provisions of the Protective Order.

REQUESTS FOR PRODUCTION OF DOCUMENTS AND THINGS

REQUEST FOR PRODUCTION NO. 1:

All communications between You and BDSI regarding patents relating to any lingual, sublingual, or buccal film formulation containing buprenorphine, including, but not limited to, the '167 Patent.

REQUEST FOR PRODUCTION NO. 2:

Communications, including agreements and/or contracts, between You and BDSI relating to BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine.

REQUEST FOR PRODUCTION NO. 3:

All documents relating to ARx's role regarding BDSI's NDA and/or BELBUCA, including research and development, manufacture or production, and/or ingredient sourcing.

REQUEST FOR PRODUCTION NO. 4:

Correspondence or other communication relating to BDSI's NDA, BELBUCA, and any other lingual, sublingual or buccal film formulation containing buprenorphine, including communications between ARx and BDSI.

REQUEST FOR PRODUCTION NO. 5:

Communications with Plaintiff and/or with any current or former employee or consultant of Plaintiff.

REQUEST FOR PRODUCTION NO. 6:

All documents relating to the research and development of BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including the formulation of and selection of components for any such film formulation.

REQUEST FOR PRODUCTION NO. 7:

All agreements and communications between You and any Third Party relating to any processes, procedures, materials, or equipment involved in or related to BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI.

REQUEST FOR PRODUCTION NO. 8:

All documents relating to the manufacturing process(es) of BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including, but not limited to, specifications, technical documentation, requirements specifications, design specifications, manufacturing recipes, manufacturing instructions, manufacturing flows, data sheets, measurements and/or data monitored or collected during the manufacturing process.

REQUEST FOR PRODUCTION NO. 9:

All registration records and batch records for BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI.

REQUEST FOR PRODUCTION NO. 10:

All documents relating to testing protocols, testing procedures, testing parameters, testing results, sampling plans, sampling protocols, or industry standards for sampling plans or sampling protocols, of BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI.

REQUEST FOR PRODUCTION NO. 11:

All documents relating to the physical, structural, and chemical characteristics of BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including the amounts of each component included therein and the reasons for its inclusion.

REQUEST FOR PRODUCTION NO. 12:

All documents relating to the decision to use each excipient in BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, and the reasons for it, including all alternative excipients considered and all research and testing related thereto.

REQUEST FOR PRODUCTION NO. 13:

All documents and communications relating to ARx's knowledge, consideration, and/or investigation of patents relating to any lingual, sublingual, or buccal film formulation containing buprenorphine, including, but not limited to, the '167 Patent.

REQUEST FOR PRODUCTION NO. 14:

All documents relating to any legal and/or technical opinions obtained by BDSI and/or ARx for the purpose of evaluating the scope, infringement, or validity of patents relating to any lingual, sublingual, or buccal film formulation containing buprenorphine, including, but not limited to, the '167 Patent.

REQUEST FOR PRODUCTION NO. 15:

All documents relating to the development of the manufacturing process use to make BELBUCA and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including different apparatuses, settings, configurations, specifications, or parameters considered or tried during development and the reasons such apparatuses, setting, configurations, specifications, or parameters were rejected or adopted for use.

REQUEST FOR PRODUCTION NO. 16:

All documents relating to the monitoring and engineering of the manufacturing equipment and process used to make BELBUCA and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including but not limited to data reflecting any engineering or manufacturing parameter, including but not limited to engineering of manufacturing equipment, temperature, airflow, fluid flow, velocity, and pressure.

AO 88A (Rev. 12/20) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

Eastern District of North Carolina

Aquestive Therapeutics, Inc.
Plaintiff
v.
BioDelivery Sciences International, Inc.
Defendant

Civil Action No. 5:19-cv-00505-D

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: ARx, LLC at 400 Seaks Run Road, Glen Rock, PA 17327

(Name of person to whom this subpoena is directed)

☑ Testimony: YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must promptly confer in good faith with the party serving this subpoena about the following matters, or those set forth in an attachment, and you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about these matters: See Attachment A.

Place:	Date and Time:
Steptoe & Johnson LLP 1330 Connecticut Avenue NW Washington, DC 20036	2/16/2022 9:00am ET, or at such a date, time, and location to be agreed upon by counsel

The deposition will be recorded by this method: Stenographic means and will be videotaped

☐ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 01/11/2022

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Aquestive Therapeutics, Inc., who issues or requests this subpoena, are:
E. Bradley Evans, Ward & Smith, P.A., Post Office Box 8088, Greenville, NC 27835, ebe@wardandsmith.com, (252) 215-4025

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 5:19-cv-00505-D

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

DEFINITIONS

1. The terms "Plaintiff" and "Aquestive" mean Plaintiff Aquestive Therapeutics, Inc., and include, without limitation, all parents, subsidiaries, affiliates, divisions, officers, directors, employees, partners, agents, attorneys, and representatives of Aquestive, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Aquestive.

2. The terms "Defendant" and "BDSI" mean Defendant BioDelivery Sciences International, Inc., and include, without limitation, all parents, subsidiaries, affiliates, divisions and other entities owned or controlled by Defendant, if any; all officers, directors, employees, partners, agents, attorneys, representatives and owners (whether direct or indirect and legal, beneficial or otherwise) of entities owned or controlled by Defendant, if any, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of Defendant or of any subsidiary, affiliate, division or entity owned or controlled by Defendant.

3. The terms "ARx," "You" and "Your" mean ARx, LLC, and include, without limitation, all parents, subsidiaries, affiliates, divisions and other entities owned or controlled by You, if any; all officers, directors, employees, partners, agents, attorneys, representatives and owners (whether direct or indirect and legal, beneficial or otherwise) of entities owned or controlled by You, if any, and any consultants, experts, investigators and other persons acting or purporting to act on behalf of You or of any subsidiary, affiliate, division or entity owned or controlled by You.

4. The term "the '167 Patent" means U.S. Pat. No. 8,765,167.

5. The term "BDSI's NDA" means BDSI's New Drug Application ("NDA") No. 207932, submitted under 21 U.S.C. § 355(b)(2), seeking approval to manufacture, market and sell

BELBUCA throughout the United States, which was approved by the FDA on October 23, 2015, including any amendments and communications to or from the FDA relating to the NDA.

6. The terms "BELBUCA" and "Accused Product" mean BDSI's BELBUCA® (buprenorphine) buccal films that are the subject of BDSI's NDA in the following doses of buprenorphine: 75, 150, 300, 450, 600, 750, and 900 mcg.

7. The term "FDA" means the United States Food and Drug Administration.

8. The terms "Person" and "Persons" mean any individual or entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

9. The term "Entity" means any entity, including, without limitation, a corporation, municipal corporation, partnership, joint venture, firm, trust, group association, governmental agency, commission, bureau or department and any division, department or other unit thereof.

10. The term "Third Party" means and includes any Person or Entity other than Defendant and Plaintiff.

11. The term "communication" means the transmission of information (in the form of facts, ideas, inquiries or otherwise), whether orally or in writing (e.g., by fax, email, or any other means or medium), and includes without limitation all documents reflecting or concerning such communications.

12. The terms "thing" or "things" shall be defined as synonymous in meaning and equal in scope to the use of that term in Fed. R. Civ. P. 34(a) and includes any tangible object other than a document.

13. The term “document” is used in the broadest sense contemplated by Federal Rule of Civil Procedure 34 and includes the terms “writings and recordings,” “photographs,” “originals,” and “duplicate” as defined in Federal Rule of Evidence 1001 and includes, without limitation, any and all tangible documents and things responsive to the document request as well as any other information regardless of the form in which the information has been stored, including electronically stored information within Your possession, custody, or control.

14. The term “electronically stored information” means any document, communication, code, architecture, internal software comments, or any other data or information present or stored on any computer, internal or external hard drive, jump drive, diskette, compact disc, database, server, or any other device or system capable of storing electronic files or information.

15. The terms “reflecting,” “concerning,” “regarding,” “relating to,” or “referring to” mean all documents or information that comprises, evidences, constitutes, describes, explicitly or implicitly refers to, was reviewed in conjunction with, or was generated as a result of the subject matter of the request, including but not limited to all documents that reflect, record, memorialize, discuss, evaluate, consider, review, report, or relate to the subject matter of the request.

16. The term “employee” means any person currently or formerly serving, acting, or existing as an employee or agent, including employees, agents, attorneys, partners, associates, financial advisors, consultants, investigators, and any other person acting on behalf of the person referred to, pursuant to the authority of the person referred to, or subject to the control of the person referred to.

17. The term “identify” when used with respect to an activity, an occasion or a transaction means and refers to providing: the date of the act; the identity of the persons who

participated in the act; the identity of each person who witnessed such act; and a general description of the act.

18. The term "identify" when used with respect to persons means to state the person's name, title (or job description), present or last known employer or business association, and present or last known address.

19. The term "identify" when used with respect to documents means to provide the following information irrespective of whether the document is deemed privileged or subject to any claim of privilege:

a) the title or other means of identification of the document;

b) the date of the document;

c) the author of the document;

d) the recipient or recipients of the document;

e) the subject matter of the document;

f) the present location of any and all copies of the document in the possession, custody or control of Defendants; and

g) the names and current addresses of any and all persons who have possession, custody, or control of the document or copies thereof.

20. "And" and "or" shall be construed conjunctively and disjunctively so as to acquire the broadest possible meaning.

21. The terms "any," "all," or "each" shall be construed as "any, all and each."

22. The singular and masculine form of a noun or pronoun shall embrace, and shall be read and applied as, the plural or the feminine or neuter, as the particular context makes appropriate or permits to obtain the broadest possible meaning.

23. The use of the singular form of any word shall include the plural and vice versa.

DEPOSITION TOPICS

DEPOSITION TOPIC NO. 1:

Communications between You and BDSI regarding patents relating to any lingual, sublingual, or buccal film formulation containing buprenorphine, including, but not limited to, the '167 Patent.

DEPOSITION TOPIC NO. 2:

Communications, including agreements and/or contracts, between You and BDSI and between You and any Third Party relating to BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine.

DEPOSITION TOPIC NO. 3:

ARx's role regarding BDSI's NDA and/or BELBUCA, including research and development, manufacture or production, and/or ingredient sourcing.

DEPOSITION TOPIC NO. 4:

Correspondence or other communication relating to BDSI's NDA, BELBUCA, and any other lingual, sublingual, or buccal film formulation containing buprenorphine, including communications between ARx and BDSI and between ARx and any Third Party.

DEPOSITION TOPIC NO. 5:

Communications with Plaintiff and/or with any current or former employee or consultant of Plaintiff.

DEPOSITION TOPIC NO. 6:

ARx's knowledge of the research and development of BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including the formulation of and selection of components for any such film formulation.

DEPOSITION TOPIC NO. 7:

Agreements between You and any Third Party relating to any processes, procedures, materials, or equipment involved in or related to BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI.

DEPOSITION TOPIC NO. 8:

Testing or sampling performed by or on behalf of ARx or BDSI relating to BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including the protocols, procedures, parameters, industry standards, specifications, and/or results of any such testing or sampling.

DEPOSITION TOPIC NO. 9:

The physical, structural, and chemical characteristics of BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including the amounts of each component included therein and the reasons for its inclusion.

DEPOSITION TOPIC NO. 10:

The decision to use each excipient in BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, and the reasons for it, including all alternative excipients considered and all research and testing related thereto.

DEPOSITION TOPIC NO. 11:

ARx's knowledge, consideration, and/or investigation of patents relating to any lingual, sublingual, or buccal film formulation containing buprenorphine, including, but not limited to, the '167 Patent.

DEPOSITION TOPIC NO. 12:

Any legal and/or technical opinions obtained by BDSI and/or ARx for the purpose of evaluating the scope, infringement, or validity of patents relating to any lingual, sublingual, or buccal film formulation containing buprenorphine, including, but not limited to, the '167 Patent.

DEPOSITION TOPIC NO. 13:

The manufacturing process used to make BELBUCA and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including different apparatuses, settings, configurations, specifications, or parameters considered or tried during development and the reasons such apparatuses, setting, configurations, specifications, or parameters were rejected or adopted for use.

DEPOSITION TOPIC NO. 14:

The monitoring and engineering of the manufacturing equipment and process used to make BELBUCA and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI, including but not limited to data reflecting any engineering or manufacturing parameter, including but not limited to engineering of manufacturing equipment, temperature, airflow, fluid flow, velocity, and pressure.

DEPOSITION TOPIC NO. 145:

ARx's role regarding registration records and batch records for BDSI's NDA, BELBUCA, and/or any other lingual, sublingual, or buccal film formulation containing buprenorphine for or on behalf of BDSI.